



NEWS RELEASE

For Immediate Release

TOVIAZ[®], is now available for OAB patients in Malaysia

New treatment demonstrates proven efficacy

Kuala Lumpur, 10 October 2011 – Toviaz[®] (fesoterodine fumarate), an extended release tablets for the treatment of overactive bladder (OAB) symptoms is now available in Malaysia, the latest country to approve the new medication in addition to Philippines, Korea and Indonesia within the Asia continent. The new once-daily Toviaz can significantly reduce the number of urge urinary incontinence episodes and the frequency of urination over 24 hours, symptoms of OAB that can significantly impact patients' lives. Overactive bladder is a bothersome medical condition yet still remains highly undertreated.

“Toviaz data demonstrated efficacy and safety based on two large 12-week Phase III clinical studies of 1,971 OAB patients. In one of the studies, patients showed up to an 88 percent median reduction in urge urinary incontinence with Toviaz 8 mg versus 50 percent with placebo. Treatment with Toviaz 8 mg reduced the number of urinations per day by up to 19 percent compared to an 11 percent reduction with placebo treatment. Reductions in wetting accidents with Toviaz were seen as early as week two of treatment and maintained over 12 weeks,” said Dr Eric Guan, Pfizer Head / Vice President of Emerging Market Primary Care.

Many people do not give much thought about it - the act of emptying the bladder, a simple physiological function. However, for Overactive Bladder (OAB) sufferers, it is a function which they have little control over and affects their quality of life tremendously. Overactive Bladder (OAB) is a medical condition associated with involuntary contractions of the bladder muscles. It is a serious, widespread, under-presented and under-treated condition which can affect people of all ages, yet can be treated easily.

For the first time in Asia, a large-scale population based study has been conducted to access the prevalence of OAB in Asia. The results from Chinese EPIC³ research has shown that many people in Asia are suffering in silence and ignorance, subjecting themselves to

³ Ong M., Choi A. Prevalence of Incontinence and Overactive Bladder: Results from the Chinese EPIC Study, Poster Presentation at the 24th Annual European Association of Urology Congress, Stockholm, Sweden, 17th-21st, March 2009

needless embarrassment, discomfort and health risks due to a common medical disorder which could be managed by a simple visit to the doctor.

An estimated one in six people in the region (over the age of 40) suffer from OAB, without realizing that it's a medical condition that is common yet easily treatable. The recently completed Chinese EPIC study also found that a full 15.8 percent of 6,612 people over the age of 18, surveyed in China, Hong Kong and Taiwan, suffer from Overactive Bladder (OAB), a condition associated with involuntary contractions of the bladder muscle.

Studies in Europe and the US point to similar results. 11.8% of 19,165 people who were surveyed across Canada, Germany, Italy, Sweden and the UK suffered from OAB², whilst 16.5% of 5,204 people over 18 years old surveyed in the US were also reported to suffer from OAB³.

“The effects that OAB can have on one's life is considerable. It has been linked to negative emotional and physical well-being, as well as diminished work place productivity, social and sexual relationships,” said Dr Guan.

Dr Guan added “The survey was conducted over the phone with a total of 6,612 participants from China, Hong Kong and Taiwan which revealed that 15.8% of participants suffer from OAB.

“The study substantiated what the medical fraternity believed in all this time, i.e. OAB sufferers are negatively impacted on most emotional attributes such as depression, feeling sad, experiencing cycling spells, loneliness and restless sleep. Results also revealed that sufferers lose 15% of their work time due to their urinary symptoms. But only less than 30% ever seek treatment,” said Dr Guan.

A similar study, the CLINIC study, was conducted in Malaysia which provides an insight into OAB among patients attending outpatient clinics. Although number of respondents were on a smaller scale, 450 patients, but the results mirror that of the EPIC study, i.e. 37% of Malaysians never discussed their urinary problems with their doctors⁴

“The results from the CLINIC study indicated 6% of Malaysians were categorized as ‘Probable OAB’ indicating that these respondents scored highly in their responses to OAB symptoms. Out of these probably OAB respondents, 80% believe they are still able to cope

² Irwin DE et al. Population based survey of Urinary Incontinence, Overactive Bladder and other Lower Urinary Tract Symptoms in Five Countries: Results of the EPIC Study. *European Urology*, 2006

³ Stewart WF, Van Rooyen JB, Cundiff GW, et al. Prevalence and burden of overactive bladder in the United States. *World J Urol* 2003;20:327–36.

⁴ A presentation by the Pfizer regional on OAB Clinic Study on Malaysia was also presented to the members of the media

with their symptoms whilst 30% felt these problems were not important to discuss with their physician. These results underscore the high prevalence but under-reporting or under-diagnosis of OAB sufferers,” said Associate Professor Dr Ong Teng Aik, consultant urologist, Division of Urology, University Malaya Medical Centre (UMMC)

“In addition to the negative impact on quality of life, OAB sufferers often develop elaborate strategies to cope with their symptoms such as sitting in aisle seats, wearing absorption diapers, carrying spare clothes and even containers to help them manage their symptoms.”

“There is a misconception that OAB is an inevitable part of aging. I would like to stress that it is not necessarily the case and OAB should not be considered normal among adults of any age. OAB symptoms include urgency to urinate, frequency of urination, urge urinary incontinence (involuntary leakage) and nocturia (patient wakes at night one or more times to void). “Any individuals experiencing these symptoms are urged to seek advice from their healthcare professionals,” advised Prof Ong.

OAB treatment options include behavioural and / or pharmacotherapy. The former helps OAB sufferers better manage their symptoms such as pelvic floor muscle exercises, bladder training or altering drinking patterns while pharmacotherapy has been found to be effective in treating OAB.

In addition to behavioural therapy, the first-line medical therapy for OAB, muscarinic receptor antagonists, may be prescribed. “The drug works by relaxing and reducing bladder contraction preventing unwanted frequent urination and leaks, thereby reducing the symptoms experienced by OAB sufferers with a significant improvement in quality of life,” said Prof Ong.

OAB is a serious, widespread and under-treated condition that is growing in prevalence and burden. It can be associated with burdensome co-morbidities, such as falls and fractures, urinary tract and skin infections, sleep problems and depression,” added Prof Ong.

“Pfizer is a leader in the field of urology with significant experience in meeting the needs of patients with OAB. The approval for the company’s latest product, TOVIAZ, is good news for patients and treating physicians in Malaysia. Clinical trials with Toviaz showed strong efficacy and favorable tolerability, and the ability to titrate the dose of Toviaz allows physicians flexibility in treating each patient based on individual history and need,” commented Dr. Vicknesh Welluppillai, Medical Director of Pfizer Malaysia.

About TOVIAZ

TOVIAZ® (fesoterodine fumarate) is indicated for the treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur in patients with overactive bladder syndrome.

TOVIAZ is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow angle glaucoma, myasthenia gravis, severe ulcerative colitis, toxic megacolon, severe hepatic impairment, simultaneous use of potent CYP3A4 inhibitors in patients with moderate to severe hepatic or renal impairment, and known hypersensitivity to TOVIAZ, to peanut or soya, or to other recipients. TOVIAZ should be used with caution in patients with significant bladder outlet obstruction at risk of urinary retention, gastrointestinal obstructive disorders, renal impairment, hepatic disease, autonomic neuropathy, gastro-oesophageal reflux and/or who are concurrently taking medicinal products (eg, oral bisphosphonates) that can cause or exacerbate oesophagitis, decreased gastrointestinal motility, and risk factors for QT prolongation. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

TOVIAZ may cause mild to moderate anti-muscarinic effects. Dry mouth was the most frequently reported adverse event (TOVIAZ 29% versus placebo 8.5%).

About Pfizer Malaysia

Pfizer Malaysia is committed towards Working Together for a Healthier World™. We apply our global resources and strive to set the standard for quality, safety and value of medicines to improve the health and well-being of Malaysians at every stage of life. Our diversified health care portfolio includes human biologic, small molecule medicines and vaccines in Biopharmaceuticals, as well as a wide range of Nutritional products.

We also collaborate closely with public and private health care providers, and communities to support and expand access to reliable, affordable health care in Malaysia. Pfizer Malaysia began operations in 1964, and every day, some 500 colleagues throughout the country work to advance wellness and make a difference for all who rely on us.

Wyeth is now a whollyowned subsidiary of Pfizer Inc. The merger of Wyeth Malaysia and Pfizer Malaysia entities may be pending in various jurisdictions and integration is subject to completion of various local legal and regulatory obligations.

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